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RESEARCH**

APPLICATION NUMBER:

22-004

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

16 AUGUST 2006

NDA: 22-004

Drug Product Name

Proprietary: N/A

Non-proprietary: ciclesonide nasal spray

Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
12/21/2005	12/22/2006	8/1/2006	8/8/2006

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: ALTANA Pharma US, Inc.

Address: 210 Park Avenue, Florham Park, NJ 07932

Representative: Cheryl Czachorowski

Telephone: 973-514-4271

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA
 2. **SUBMISSION PROVIDES FOR:** A preserved nasal spray
 3. **MANUFACTURING SITE:** ALTANA Pharma AG
Robert-Bosch-Strasse 8
D-78224 Singen
Germany
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Aqueous suspension of ciclesonide in a glass bottle with a plastic metered dose pump, _____ * ciclesonide/actuation, _____
_____ 120 actuations/bottle
 5. **METHOD(S) OF STERILIZATION:** N/A
 6. **PHARMACOLOGICAL CATEGORY:** corticosteroid
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** This review covers validation of the drug product preservative system.

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Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – This submission is recommended for approval on the basis of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A

II. Summary of Microbiology Assessments

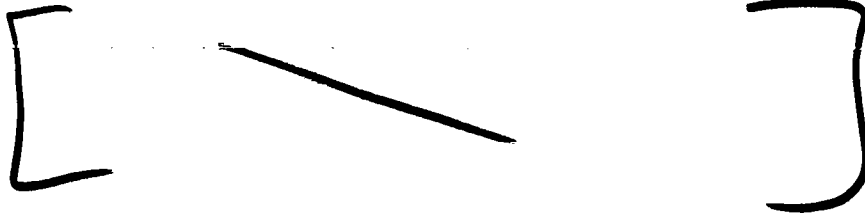
- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The drug product is a preserved aqueous solution.
- B. Brief Description of Microbiology Deficiencies** – N/A
- C. Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. Reviewer's Signature** _____
Bryan S. Riley, Ph.D.
- B. Endorsement Block** _____
Stephen Langille, Ph.D.
- C. CC Block**
N/A

Product Quality Microbiology Assessment

The drug product is a non-sterile, preserved nasal spray. This review covers the anti-microbial effectiveness test for the drug product formulation.



ADEQUATE

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Bryan Riley
8/23/2006 08:01:11 AM
MICROBIOLOGIST

Stephen Langille
8/23/2006 08:14:03 AM
MICROBIOLOGIST